NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane - Reno, NV 89509

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑New Pharmacy or ☐Ownership Chan Check box below for type of ownership and				inges: PH
☐ Publicly Traded Corporation - Pages 1,3	2,3,7	Partners	hip - Pages 1,2,5	5,7
	es 1,2,4,7	☐ Sole Ow	ner – Pages 1,2,6	5,7
GENERAL INFORMATION to be comp	oleted by al	types of ow	<u>nership</u>	
Pharmacy Name: CALIFORNIA SPECIA	TY PHARMA	CY		
Physical Address: 12466 E WASHINGTO	N BLVD			
Mailing Address: 12466 E WASHINGTO	N BLVD			
City: Whittier	_ State:	CA	Zip Code:	90602
Telephone: _877-602-7779	Fax:866	-853-6555		- 1
Toll Free Number: <u>877-602-7779</u>	(Re	quired per N	AC 639.708)	
E-mail:info@csprx.com	_ Wel	osite:www.	csprx.com	
Managing Pharmacist: ETHAN HUYNH		Lio	cense Number:	58232
TYPE OF PHARMACY	AND	SERVICE	S PROVIDED	
Yes/No		Yes/No		
☑ □ Retail		⊠ □ Off	-site Cognitive Se	rvices
☐ ☐ Hospital (# beds	_)	□ Æ Par	renteral **	
□ □ Internet		□ □ Par	renteral (outpatier	it)
□ □ Nuclear		D Ou	tpatient/Discharge	
☐ ☑ Ambulatory Surgery	Center	□ D Ma	il Service	
☐ ☐ Community		□ D Lor	ng Term Care	
☑ ☐ Other: Home Infusion	on	□ D Ste	rile Compounding	**
		D Z NO	n Sterile Compour	nding
All boxes must be checked		□ ⊅ Ma	il Service Sterile (Compounding **
For the application to be co	nplete	□ Oth	ner Services: <u>Spe</u>	ecialty Pharmacy

92853

^{**}If you check "yes" on any of these types of services, you will be <u>required</u> to make an appearance at the board meeting,

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

with ss ea)? Yes □ No ☒
with Yes □ No ⊠
with any d citation, Yes □ No ⊠
with any nolo Yes □ No ⊠
with any stration cility)? Yes □ No ☒
xplanation must be attached order, agreement, or other
documentation are true and vada regulating the on of this permit.
ents thereof. I hereby certify ion are true, accurate and agents, servants and al, social and moral roper or desirable.
es or stamps
110/2016
/ Page 2
\$ 500.00

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State	of Incorporation:	California				
Parent	Company if an	y: <u>N/A</u>				
Mailing	Address: 1240	66 E WASHINGTO	N BLVD			
City: _	Whittier		State: CA	Zip:	90601	
Teleph	none: <u>877-602-7</u>	779	Fax: _866	-853-6555		
Contac	ct Person: _Etha	an Huynh, PharmD				
For an	y corporation no	on publicly traded, o	lisclose the follo	wing:		
1)	List top 4 perso	ens to whom the sh	ares were issued	by the corpora	ation?	
	a) ANIL BADLA	ANI	12620 Liddin	igton St Cerritos	, Ca 90703	
	/	ame	Address	<u> </u>		
	b) BHAVESH D	ESAI	1823 Comme	rcenter Drive Sa	an Bernardino, CA	4 92408
	/	ame	Address			
	c) SUMIT DES	AI	1823 Comme	ercenter Drive Sa	an Bernardino, C	A 92408
	/	ame	Address			
	d)					
		ame	Address			
2)	Provide the nur	mber of shares issu	ed by the corpor	ration900	,000	
2)	\\/hat was the	orica paid par chare	2 \$0.667			
3)		orice paid per share				
4)	What date did	the corporation act	ally receive the	cash assets?	03/09/2010	
5)	Provide a copy	of the corporation'	s stock register e	evidencing the	above informat	ion
l ist ar	ny physician sha	reholders and perc	entage of owner	ship.		
		aronolasio ana psi			0/	
Name						
Name	. N/A 				%:	
Hours	of Operation 1	for the pharmacy:				
Mond	ay thru Friday _	9:00 am	pm	Saturday	CLOSED am	pn
	Sunday CL	OSED _{am}	pm	24 Hours	: <u></u>	
		cense is not require			s a Nevada bus	siness
licens	e please provide	e the number:				Page 4

Out of State Pharmacy applicant - Change of Address

Ethan Huynh [ethan@csprx.com]

Sent: Tuesday, August 9, 2016 9:43 AM

To: Pharmacy Board

Cc: Sumit Desai [sumit@csprx.com]; Bhavesh Desai [bdesai@guardianrx.us]; George Kridner [george@csprx.com]

Attachments: CA PHY 54320 Retail Pharma~1.pdf (5 MB)

Dear Candy/Licensing team,

Thank you for taking my call this morning. From our conversation, since our application is still pending final approval and our address location has changed this is to notify BOP that our address has changed from 12466 E WASHINGTON BLD, WHITTIER, CA 90602 to our new address: 13027 HADLEY ST, SUITE B, WHITTIER CA 90601.

Attached also is our new issued permit from CA BOP reflecting the new and current address.

Please ensure that the letter being issued to notify us of the details regarding the appearance for the September Board meeting is sent to 13027 Hadley St, Suite B, Whittier CA 90601.

Thank you,

Ethan Huynh, Pharm.D. Vice President, Pharmacy Operations California Specialty Pharmacy 13027 Hadley St, Suite B Whittier, CA 90601 Phone (877) 602-7779 | Fax (866) 853-6555 www.csprx.com

CONFIDENTIALITY NOTICE: This communication and any attachments may contain confidential and/or privileged information for the use of the designated recipients named above. If you are not the intended recipient, you are hereby notified that you have received this communication in error and that any review, disclosure, dissemination, distribution or copying of it or its contents is prohibited. If you have received this communication in error, please notify the sender immediately by telephone and destroy all copies of this communication and any attachments.

[&]quot;Discover the difference of an independent specialty pharmacy"

STATEMENT OF RESPONSIBILITY FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I,Ethan Huynh, PharmD
Responsible Person of _CALIFORNIA SPECIALTY PHARMACY
hereby acknowledge and understand that in addition to the corporation's, any owner(s),
shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy law
that may occur in a pharmacy owned or operated by said corporation.
I further acknowledge and understand that the corporation's, any owner(s), shareholder(s)
or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a
pharmacy owned by or operated by said corporation.
I further acknowledge and understand that the corporation's, any owner(s), shareholder(s)
or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision
of any local, state or federal laws or regulations pertaining to the practice of pharmacy.
Effect Office A Submit Application no conjugar stramps
Original Signature of Person Authorized to Submit Application, no copies or stamps
Ethan Huynh, PharmD 05/13/2016
Print Name of Authorized Person Date

www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY DEPARTMENT OF CONSUMER AFFAIRS GOVERNOR EDMUND G. BROWN JR.

May 10, 2016

CALIFORNIA SPECIALTY PHARMACY 12466 E WASHINGTON BLVD WHITTIER CA 90602

California State Board of Pharmacy License Verification

This document reflects the license status of the person or entity identified below on this date with the California State Board of Pharmacy. It may be used as prima facie evidence of the facts recited below pursuant to California Business and Professions Code section 162.

Licensee Name:

CALIFORNIA SPECIALTY PHARMACY

License Type:

PHARMACY

License Number: PHY 50315

Status:

ACTIVE

Issue Date:

06/24/10

Expiration Date:

06/01/16

Address of Record: 12466 E WASHINGTON BLVD WHITTIER CA 90602

Disciplinary Action: NO RECORD OF DISCIPLINARY ACTION

Bv

Barbera Schleicher

Public Inquiry Analyst

(916) 574-7922

Virginia Herold Executive Officer

Barbera.Schleicher@dca.ca.gov

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane - Reno, NV 89509 - (775) 850-1440

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

□ New Pharmacy	Ownership Change number if making changes: PHO2510)
☐ Publicly Traded Corporation – Pages 1,2,3,7 ☐ Non Publicly Traded Corporation – Pages 1,2,4	☐ Partnership - Pages 1,2,5,7 ☐ Sole Owner – Pages 1,2,6,7
Please check box for type of ownership and co	
GENERAL INFORMATION to be completed I	
Pharmacy Name: R4R Compound	
Physical Address: 2950 Thousan	doaks
Mailing Address: SamL	
City: San Antonio State	e: <u>TX</u> zip Code: <u>78232</u>
Telephone: 210 424 0025 Fax:	210 424-0026
Toll Free Number: 800 250 6232	(Required per NAC 639.708)
E-mail: pharmacy@taloncompounding	Website: taloncompounding.com
Managing Pharmacist: Rachel Pittman	License Number: 51474
TYPE OF PHARMACY AND	SERVICES PROVIDED
Yes/No	Yes/No
√ □ Retail	□ ☑ Off-site Cognitive Services
□	□ √☐ Parenteral **
□ ✓ Internet	□ √ Parenteral (outpatient)
□	□ ☑ Outpatient/Discharge
□ √ Ambulatory Surgery Center	☑
□ ☑ Community	□ √☑ Long Term Care
□	□ ☑ Sterile Compounding **
V	□ ☑ Non Sterile Compounding
All boxes must be checked	☐ ☑ Mail Service Sterile Compounding **
For the application to be complete	□ ☑ Other Services:
	v

^{**}If you check "yes" on any of these types of services, you will be <u>required</u> to make an appearance at the board meeting,

APPLICATION FOR OUT-OFSTATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Origin	al Signature of Pers	Son Authorized to Submit	Application, no copies or stam	nps
penalty hereby any inv	of perjury, that the in authorize the Nevad restigation(s) of the b	nformation furnished on this a State Board of Pharmacy	know the contents thereof. I he sapplication are true, accurate a , its agents, servants and emploal and moral background, qualification.	nd correct. I yees, to conduct
Lunder	stand that any infrac	wers given in this application of the laws of the State e grounds for the revocation	on and attached documentation a e of Nevada regulating the operation of this permit.	re true and correct. tion of an
Copie	answer to question s of any documents sition may be require	that identify the circums	gned statement of explanation tance or contain an order, agre	must be attached. eement, or other
5)	interest, ever surre	ndered a license, permit	Ider(s) or partner(s) with any or certificate of registration luntary close of a facility)?	Yes □ No
4)	interest, ever been		older(s) or partner(s) with any or entered a plea of nolo related to controlled	Yes □ No ☑
3)	interest, ever been		older(s) or partner(s) with any strative action or proceeding	Yes □ No 邙
2)		n, any owner(s), shareho been denied a license, po	older(s) or partner(s) with ermit or certificate of	Yes □ No Ⅳ
1)	any interest, ever	been charged, or convict	older(s) or partner(s) with ed of a felony or gross olea or no contest plea)?	Yes □ No
Withi	n the last five (5) ye	ars:		

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A PARTNERSHIP	General	Limited
Partnership Name: R&R Compoundi Mailing Address: 2950 Thousand Ca City, State Zip Code: San Antonio, To Telephone Number: 210 424 0025 Fax N Contact Person: Ronda Wenzel List each partner and identify whether (G)eneral or (L)	KS Dr. S1 78232 Number: 210 42	4 0026
Use separate sheet if necessary		
Rachel Sizanne Pittman Ronda Melyn Wenzel	<u>Gorl</u> <u>し</u> し	51 49
List names of 4 largest partners and percentage of ow	nership: No Of	
Name:		_%:
Name:		
Name:		_%;
Name:		_ %:
List any physician shareholders and percentage of ow	nership. NON	C
Name:		_%:
Name:		%:
Name:		%:
Name:		%:

A we are an LLC, we've used the "partnership" form because it seemed to fit

CORPORATE STATEMENT OF RESPONSIBILITY FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

1, Ronda Wonzel
Responsible Person of RER Compounding
hereby acknowledge and understand that in addition to the corporation's, any owner(s),
shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy
law that may occur in a pharmacy owned or operated by said corporation.
I further acknowledge and understand that the corporation's, any owner(s), shareholder(s)
or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a
pharmacy owned by or operated by said corporation.
. I further acknowledge and understand that the corporation's, any owner(s), shareholder(s)
or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision
of any local, state or federal laws or regulations pertaining to the practice of pharmacy.
Ronda Wensel
Original Signature of Person Authorized to Submit Application, no copies or stamps
Ronda Wenzel 5-23-16
Print Name of Authorized Person Date

а

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane - Reno, NV 89509

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

New Pharmacy or Wownership Change (Provide current license number if making changes: PH 02133

© Publicly Traded Control Non Publicly Trade	r type of ownership and complete all required forms. Corporation – Pages 1,2,3,7 ☐ Partnership - Pages 1,2,5,7 Ided Corporation – Pages 1,2,4,7 ☐ Sole Owner – Pages 1,2,6,7			
	MATION to be complet			
Pharmacy Name:	US Compounding			
Physical Address:	ress: 1270 Dons Lane Conway, AR 72032			
Mailing Address: _	P.O. Box 2709 Conway, A	R 72033		
City: Conway		State: _AR		_ Zip Code:
Telephone: 501-	327-1222 F	ax:501-49	-8383	
Toll Free Number:	(800) 718-3588	(Require	d per NAC	C 639.708)
E-mail: licensing@u	uscompounding.com	Website	www.usco	ompounding.com
Managing Pharmacist: Eddie Glover License Number: PD06232				
TYPE			RVICES	PROVIDED
TYPE Yes/N	OF PHARMACY A	ND <u>S</u>	RVICES s/No	
Yes/N	OF PHARMACY A	ND <u>S</u>	s/No	
Yes/N	OF PHARMACY A	ND S	s/No	PROVIDED te Cogneive Services
Yes/N	OF PHARMACY At	ND S	s/No	PROVIDED te Cogneive Services
Yes/N	OF PHARMACY Af O Retail Hospital (# beds)	ND S	s/No Ϫ Off-si □ Parer 风 Parer	PROVIDED te Cogneive Services iteral **
Yes/N X X X X X	OF PHARMACY At lo lo Retail Hospital (# beds)	ND S	s/No Ϫ Off-si □ Parer 风 Parer	te Cogneive Services Interal ** Interal (outpatient) Interationt/Discharge
Yes/N X X X X X X X X X X X X X	OF PHARMACY At lo	ND S	S/No ☑ Off-si □ Parer ☑ Parer ☑ Outpa □ Mail S	te Cogneive Services Interal ** Interal (outpatient) Interationt/Discharge
Yes/N X X X X X X X X X X X X X	OF PHARMACY At lo Retail Hospital (# beds) Internet Nuclear Ambulatory Surgery Cel	ND S	S/No ☐ Parer ☐ Parer ☐ Cutpa ☐ Mail S ☐ Long	te Cognitive Services Interal ** Interal (outpatient) Interal (Discharge Service
Yes/N X X X X X X X X X X X X X	OF PHARMACY At lo	ND S	No Parer Parer Coutpa Mail S Long Steril	te Cognave Services Interal ** Interal (outpatient) Interal (Discharge Service Term Care
Yes/N X X X X X X X X X X X X X	OF PHARMACY At lo	ND S	No Parer Parer Coutpa Mail S Long Steril	te Cognitive Services Interal ** Interal (outpatient) Interal (Discharge Service Term Care Interal Compounding **
Yes/N X X X X X X X X X X X X X	OF PHARMACY And It of the Items of Item	ND S	No Parer Parer Nong Steril Mail S Mail S	te Cognitive Services Interal ** Interal (outpatient) Interal ** Interal

**If you check "yes" on any of these types of services, you will be <u>required</u> to make an appearance at the board meeting,

no change from previous business model

APPLICATION FOR OUT-OF STATE PHARMACY LICENSE

This page must be submitted for all types of ownership.

Board	Use Only	Date Processed	d:		Amount:	\$500.00	<i>3</i>		
PIINT I	varne of Autr	norized Person			Date		Р	age 2	2
Eddie (animad Danas			5/3	1/6			
Origin	al Signature	of Person Autho	orized to Subr	mit Applicati	ion, no co	pies or stamp	os		
50	Debie Ik	ication and repu							
correct emplo	t. I hereby a yees, to con	outhorize the New duct any investig	vada State Bo gation(s) of th	oard of Pha e business,	rmacy, its , professio	agents, serv nal, social ar	ants and	i	
	•	stions, answers erjury, that the in						-	-
correc	t. Lundersta	t the answers gir and that any infra thorized pharma	action of the I	aws of the S	State of N	evada regula	ting the	true :	and
Copie		estion 1 through uments that iden e required.							
5)	interest, eve	poration, any ow er surrendered a or otherwise (othe	license, perr	nit or certific	cate of reg	gistration	Yes □	No	
4)	interest, eve	poration, any ower been found gu to any offense for	uilty, pled guil	ty or entere	d a plea o	fnolo	Yes □	No	X
3)	interest, eve	poration, any ow er been the subjectoroceeding relati	ect of an adm	ninistrative a	action, boa	ard citation,	Yes 🗓	No	
2)		poration, any ow c, ever been deni ?	, ,				Yes □	No	
1)	any interest	poration, any ow c, ever been char or (including by	rged, or conv	icted of a fe	lony or gr	oss	Yes □	No	X
Withir	the last five	(5) years:							

APPLICATION FOR OUT-OF-STATE PHARMACY LICENSE

OWNERSHIP IS A PUBLICY TRADED CORPORATION

Ot to fit was at a second Arkaneae	
State of Incorporation: Arkansas	als Commention
Parent Company if any: Adamis Pharmaceutic	als Corporation
Corporation Name: US Compounding, Inc	
Mailing Address: 1270 Don's Lane	
City: Conway State	e: AR Zip:
	Fax: _501-499-8383
Contact Person: Rebecca Mitchell	
the applicant shall identify the officers of that co	
Monday thru Friday <u>8:30</u> am <u>5:30</u> pm	Saturday <u>N/A</u> ampm
Sunday <u>N/A</u> ampm	24 Hours
A Nevada business license is not required, how license please provide the number:	
Must be included with the application	for a publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors.

STATEMENT OF RESPONSIBILITY FOR PHARMACIES LOCATED OUTSIDE OF NEVADA

I,Eddie Glover
Responsible Person of US Compounding
hereby acknowledge and understand that in addition to the corporation's, any owner(s),
shareholder(s) or partner(s) responsibilities, may be responsible for any violations of pharmacy la
that may occur in a pharmacy owned or operated by said corporation.
I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s)may be named in any action taken by the Nevada State Board of Pharmacy against a pharmacy owned by or operated by said corporation.
I further acknowledge and understand that the corporation's, any owner(s), shareholder(s) or partner(s) cannot require or permit the pharmacist(s) in said pharmacy to violate any provision of any local, state or federal laws or regulations pertaining to the practice of pharmacy.
Soldie Islavo
Original Signature of Person Authorized to Submit Application, no copies or stamps
Eddie Glover 5/3/16
Print Name of Authorized Person

ARKANSAS STATE BOARD OF PHARMACY

LENORA NEWSOME, P.D. President, Smackover STEPHANIE O'NEAL, P.D. Vice President, Wynne THOMAS WARMACK, P.D. Secretary, Sheridan KEVIN ROBERTSON, Pharm.D. Member, Little Rock



CHERYL BRYANT, Pharm.D. Member, Little Rock **CAROL RADER** Public Member, Fort Smith **JAMES BURGESS** Public Member, Greenwood

STEVE BRYANT, P.D.

Member, Batesville

JOHN CLAY KIRTLEY, Pharm.D. **EXECUTIVE DIRECTOR**

VERIFICATION OF LICENSURE

Address: 1270 Don's	Lane		
City: Conway	State: AR	Zip Co	ode: 72033
CENSING BOARD OF	RAGENCY: This is to certify	that the above-named w	as issued:
License #	Type of License	Date issued	Date of expiration
AR20503	Retail Pharmacy	04/11/2005	12/31/2017
⊠Active □Inac	ves please attach a copy of	the decision and a detail	□Suspended □Revokiled explanation for the ed.)
⊠Active □Inaction: (If iscipline and a copy of last this license ever be incumbered in any way)	tive □Lapsed □Pro f yes, please attach a copy of the consent agreement(s) or en revoked, suspended, limit or is it currently under invest	the decision and a detail decision & order(s) issue ed, surrendered, restricte	iled explanation for the ed.) ed, placed on probation,
⊠Active □Inaction: (If isciplinary Action: (If iscipline and a copy of its this license ever beincumbered in any way)	tive □Lapsed □Pro f yes, please attach a copy of the consent agreement(s) or en revoked, suspended, limit	the decision and a detail decision & order(s) issue ed, surrendered, restricte	iled explanation for the ed.) ed, placed on probation,
⊠Active □Inaction: (If iscipline and a copy of last this license ever be incumbered in any way)	tive □Lapsed □Profiges, please attach a copy of the consent agreement(s) or en revoked, suspended, limit or is it currently under invest	the decision and a detail decision & order(s) issue ed, surrendered, restricte	iled explanation for the ed.) ed, placed on probation,
⊠Active □Inaction: (If isciplinary Action: (If iscipline and a copy of the state of the iscumbered in any way Nancy Sweet □Inaction	tive □Lapsed □Profiges, please attach a copy of the consent agreement(s) or en revoked, suspended, limit or is it currently under invest	the decision and a detail decision & order(s) issue ed, surrendered, restricte	iled explanation for the ed.) ed, placed on probation,



1270 Don's Lane · Conway, AR 72032 · 800-718-3588

Summary of Disciplinary Actions:

(All information previously submitted to the Board)

Colorado, 2008: The licensing coordinator, who left our company in 2015, was unaware that a "zero report" needed to be submitted to the Colorado Board of Pharmacy indicating we had not dispensed any controlled substances into the state of Colorado.

Hawaii, 2010: Fined because the 2008 Colorado disciplinary action was not reported within the specified timeframe.

Colorado, 2014: A single prescription was dispensed to an unnamed horse at Colorado State University Veterinary Hospital labeled with the patient name "horse". The Colorado Board prohibited dispensing prescriptions not labeled for a specific patient at that time.

Michigan, 2014: Reciprocal fine for the 2014 Colorado fine.

Solie Glover 5/31/16

Minnesota, 2015: Disciplined for dispensing veterinary compounded preparations without a specific animal's name for each prescription.



1270 Don's Lane · Conway, AR 72032 · 800-718-3588

April 12, 2016

To Whom It May Concern:

On October 7, 2015, the South Carolina Board of Pharmacy issued an Order temporarily restricting US Compounding, Inc.'s ("USC") Non-Resident Pharmacy License pending further order. The Order provides that the restriction applies only to shipment of sterile compounded preparations into South Carolina and relates to FDA's August 2015 inspection of USC and USC's voluntary recall of sterile products aseptically compounded and packaged by USC.

The Order does not affect USC's ability to ship non-sterile compounded preparations into South Carolina. USC has been in contact with Mr. Ray Trotter, and investigator with the South Carolina Board of Pharmacy, and the Board's counsel. All requested information for the investigation has been provided and we are hopeful for a swift resolution to this restriction.

US Compounding welcomes any additional questions you might have about this matter.

Respectfully,

Rebecca Mitchell, PharmD, FIACP

VP of Regulatory & Quality

cc Licensing Department



1270 Don's Lane · Conway, AR 72032 · 800-718-3588

December 8, 2015

To Whom It May Concern:

On November 20, 2015, the Alabama Board of Pharmacy issued a Notice of Emergency Suspension of Permit ("Notice"). The Notice temporarily suspends US Compounding, Inc.'s ("USC") Alabama manufacturer/wholesaler/distributor permit pending a hearing before the Alabama Board of Pharmacy which is scheduled for January 19, 2016. The Notice generally provides that the emergency suspension relates to FDA's recent inspection of USC and USC's voluntary recall of sterile products aseptically compounded and packaged by USC.

The Notice does not affect USC's Alabama pharmacy license, which remains active and in good standing.

US Compounding welcomes any additional questions you might have about this matter.

Respectfully,

Rebecca Mitchell, PharmD, FIACP

VP of Regulatory & Quality

cc Licensing Department

STATE OF COLORADO

STATE BOARD OF PHARMACY

Wendy L. Anderson, Program Director

1560 Broadway, Suite 1300 Denver, Colorado 80202-5146 Phone (303) 894-7800 Fax (303) 894-7692 V/TDD Dial 711 for Relay Colorado www.dora.state.co.us/pharmacy

October 24, 2008

US Compounding, Inc Attn: Eddie Glover 2515 College Conway, AR 72034 Department of Regulatory Agencies

D. Rico Munn

Executive Director

Division of Registrations
Rosemary McCool
Director



Bill Ritter, Jr. Governor

RE:

Stipulation and Final Agency Order (Stip/FAO)

Case #2008-2689

IN THE MATTER OF THE DISCIPLINARY PROCEEDING REGARDING THE NON-RESIDENT PRESCRIPTION DRUG OUTLET REGISTRATION OF US COMPOUNDING, INC., REGISTRATION NO. 5611,

Dear Mr. Glover:

Enclosed you will find a copy of the fully executed Stipulation and Final Agency Order in the above-mentioned matter, which became effective October 22, 2008.

If you have any questions, or require additional information, please contact the Board's office.

Respectfully,

FOR THE COLORADO STATE BOARD OF PHARMACY

Tia Johnson

Complaint/Licensing Analyst

enclosure

CC

Joanna Lee Kaye, Assistant Attorney General

File

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BEFORE THE STATE BOARD OF PHARMACY STATE OF COLORADO

Case No. 2008-2689

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF THE DISCIPLINARY PROCEEDING REGARDING THE NON-RESIDENT PRESCRIPTION DRUG OUTLET REGISTRATION OF U.S. COMPOUNDING, INC., REGISTRATION NO. OSP-5611,

RESPONDENT PHARMACY.

IT IS HEREBY STIPULATED by and between the Colorado State Board of Pharmacy ("Board") and U.S. Compounding, Inc. ("Respondent Pharmacy"), to resolve all matters pertaining to Board Case Number 2008-2689 as follows:

- 1. The Board has jurisdiction over Respondent Pharmacy, its registration as a non-resident prescription drug outlet, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of title 12, article 22, C.R.S. (2008), otherwise known as the Pharmaceuticals and Pharmacists Act.
- 2. Respondent Pharmacy has been registered by the Board as a non-resident prescription drug outlet in the State of Colorado at all times relevant to this disciplinary action.
- 3. Respondent Pharmacy's address of record with the Board and current location is 2515 College Avenue, Conway, Arkansas 72034.
- 4. Respondent Pharmacy does not contest these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.
- 5. On or about October 29, 2007, Board staff sent informational letters to all registered non-resident pharmacies, including Respondent Pharmacy, which detailed the Board's Electronic Prescription Drug Monitoring Program (PDMP) and notified them of the requirement that all non-resident pharmacies provide the Board with copies of their DEA registrations and begin submitting data to the PDMP retroactive to July 1, 2007.
- 6. As of January 4, 2008, Respondent Pharmacy had not provided a copy of its DEA registration to the Board and had not submitted the required data to the PDMP database.
- 7. On or about January 4, 2008, Board staff sent a second letter to the pharmacies that had not complied with the October 29, 2007 letter, including Respondent Pharmacy.

- 8. As of March 3, 2008, after two notices, Respondent Pharmacy had not submitted the required data to the PDMP database for any of the required reporting periods.
- 9. On March 3, 2008, the Board initiated a complaint against Respondent Pharmacy because Respondent Pharmacy failed to comply with the data submission requirements of the PDMP.
- 10. Respondent Pharmacy does not contest that the conduct described above constitutes a violation of §12-22-708, C.R.S. and that such conduct provides grounds for disciplinary action against Respondent Pharmacy's non-resident prescription drug outlet registration.

<u>DISPOSITION</u> \$5,000.00 Fine with Surcharge and Terms

- 11. Fine with Surcharge. Respondent Pharmacy accepts the following discipline: Pursuant to §12-22-125.2(5), C.R.S., Respondent Pharmacy shall pay a fine of Five Thousand Dollars and No Cents (\$5,000.00). Respondent Pharmacy understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall impose and additional surcharge of 15% of this fine. Respondent Pharmacy shall therefore pay a total amount of Five Thousand, Seven Hundred Fifty Dollars and No Cents (\$5,750.00). The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent Pharmacy submits this signed Final Agency Order to the Board.
- 12. <u>Compliance</u>. Respondent Pharmacy shall at all times be registered with the Board, and shall comply with the data submission requirements of the PDMP.
- 13. Advisements and Waivers. Respondent Pharmacy enters into this Final Agency Order freely and voluntarily, whether or not Respondent Pharmacy has consulted with legal counsel. Respondent Pharmacy acknowledges its understanding that it has the following rights:
 - a. To have a formal notice of hearing and charges served upon it;
 - b. To respond to said formal notice of charges;
 - c. To have a formal disciplinary hearing pursuant to §12-22-125, C.R.S.; and
 - d. To appeal this Board order.

Respondent Pharmacy freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for Board's limiting the action taken against it to the sanctions imposed herein.

14 Acknowledgments. The undersigned authorized agent of Respondent Pharmacy has read this Final Agency Order in its entirety and acknowledges, whether or not Respondent Pharmacy has consulted with legal counsel, that Respondent Pharmacy understands the legal consequences and agrees that none of the terms or conditions herein are unconscionable. Respondent Pharmacy is not relying on any statements, promises or representations from the

Board other than as may be contained in this Final Agency Order. Respondent Pharmacy further acknowledges that it is not entering into this Final Agency Order under any duress.

- 15. <u>Violations</u>. Time is of the essence to this Final Agency Order. It is the responsibility of Respondent Pharmacy to take all appropriate steps to comply fully with this Final Agency Order. Respondent Pharmacy acknowledges and agrees that any violation of this Final Agency Order may be sanctioned as provided under §12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of its registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Pharmacy to comply with all terms and conditions of this Final Agency Order.
- 16. <u>Integration and Severability</u>. Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties in this case. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.
- 17. <u>Public Record</u>. Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.
- 18. <u>Effective Date</u>. This Final Agency Order shall become effective upon signature of a Board member or representative.

ACCEPTED AND AGREED BY

Authorized	Agent of Respon		Dated: 10 14 08
<u>trkans</u>	$\frac{25}{2}$. this $\frac{14}{2}$	n to before me in day of <u>OCLOV</u> ed agent of U.S. Comp	the County of FULLICY. State of 2008 by ELAIL CIMY in sounding. Inc.
NO	HIRAMINA TROTINGSINOSINC FAULKNIEN V CAMPTOGENINIEN	S ARKAL SAS 1.17 2.07-91-20 4	Miranda 180002 Notary Public
My commiss	sion expires:		Notal y Labite

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

DONE AND EFFECTIVE THIS 2001 DAY OF UND 1000, 2008.

State Board of Pharmacy

Wendy Anderson

Program Director

APPROVED AS TO FORM

JOHN W. SUTHERS Attorney General

JOANNA LEE KAYE, #20486 Assistant Attorney General

Business and Licensing Section

Attorneys for State Board of Pharmacy

1525 Sherman Street, 5th Floor Denver, Colorado 80203 Telephone: (303) 866-6170

FAX: (303) 866-5395 *Counsel of Record

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within STIPULATION AND FINAL AGENCY ORDER upon all parties herein by depositing copies of same in the United States mail, postage prepaid, at Denver, Colorado this Andrew day of Coronal 2008, addressed as follows:

U.S. Compounding, Inc. 2515 College Avenue Conway, Arkansas 72034

And through interagency mail to:

Joanna Lee Kaye Assistant Attorney General Colorado Department of Law

5

BOBBI W.Y. LUM-MEW 6299
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamchameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: 586-2660

Attorney for Department of Commerce and Consumer Affairs

Signed notarized paid Paid 15-24-10

BOARD OF PHARMACY DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS STATE OF HAWAII

In the Matter of the Miscellaneous Permit of)	PHA 2010-26-L
US COMPOUNDING, INC.,) Respondent.)	SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER: EXHIBIT "1"
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SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner. DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS'
REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"),
through its undersigned attorney, and Respondent US COMPOUNDING, INC. (hereinafter
"Respondent"), enter into this Settlement Agreement on the terms and conditions set forth
below.

A <u>UNCONTESTED FACTS</u>

1. At all relevant times herein, Respondent was permitted by the Board of Pharmacy (hereinafter the "Board") as a pharmacy under Miscellaneous Permit Number PMP 467. Permit Number PMP 467 was issued on or about May 2, 2006. The permit will expire on or about December 31, 2011.

- Respondent's mailing address for purposes of this action is 2515 College Avenue,
 Conway, AR 72034.
- 3. Respondent submitted information that it had been disciplined in the State of Colorado on a renewal form received by the Department of Commerce and Consumer Affairs in late November 2009.
- 4. RICO alleges Respondent entered into a Stipulation and Final Agency Order with the Colorado State Board of Pharmacy in In the Matter of the Disciplinary Proceeding Regarding the Non-Resident Prescription Drug Outlet Registration of U.S. Compounding, Inc., Registration No. OSP-5611. A true and correct copy of the October 22, 2008 Stipulation and Final Agency Order is attached as Exhibit "1." Although the action was disclosed at the time of renewal, Respondent failed to report the action within thirty (30) days as required by law.
- 5. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes ("HRS") § 436B-19(15) (failure to report disciplinary action within thirty (30) days) and § 436B-19(13) (disciplinary action in another jurisdiction).
- 6. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. <u>REPRESENTATIONS BY RESPONDENT:</u>

- 1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.
- 2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

- 3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.
- 4. Respondent being at all times relevant herein permitted as a pharmacy by the Board acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of permits and administrative fines, if the foregoing allegations are proven at hearing.
- 5. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's permit
- 6. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.
- 7. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2010-26-I.
- 8. Respondent understands this Settlement Agreement is public record pursuant to Hawaii Revised Statutes chapter 92F.

C. TERMS OF SETTLEMENT:

1. Administrative fine. Respondent agrees to pay a fine in the amount of TWO
THOUSAND FIVE HUNDRED AND NO/100 DOLLARS (\$2,500.00). Payment shall be made
by cashier's check or money order made payable to "DCCA - Compliance Resolution
Fund" and mailed to the Regulated Industries Complaints Office, Atm: Bobbi W.Y. Lum-Mew,

- Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this fully executed Settlement Agreement is returned to RICO.
- 2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph(s) C.1 above, Respondent's permit shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of the permit to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new permit until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become permitted again, Respondent must apply to the Board for a new permit pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.
- 3. <u>Possible further sanction</u>. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of pharmacies in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.
- 4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5, C.6, C.7 and C.8 below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.
- 5. <u>No Objection if Board Fails to Approve</u>. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser

,"我是你就是你的,我们就是你的,我们就是你的,我就是你的,我们就是你的,我们就是我的人的是我的,我们是我的人的,我们就是我们,我们们会

remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

- 6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.
- No Reliance on Representations by RICO Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.
- 8. Complete Agreement This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

DATED:				
	(CITY)	(STATE)	,(D.	ATE)
		US COMPOUN	DING, INC.	
		By: Solar Its	e Move	
DATED:	Honolulu, Hawaii,			•

BOBBI W.Y. LUM-MEW

Attorney for Department of Commerce and Consumer Affairs

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF US COMPOUNDING, INC.; SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER: CASE NO. PHA 2010-26-L: EXHIBIT "1"

APPROVED AND SO ORDERED: BOARD OF PHARMACY STATE OF HAWAII

ELWIN D.H. GOO Chairperson	DATE
MARK E. BROWN Vice-Chairperson	LAURIE H. Y. KAWAMURA
GARRETT A. LAU	KARL H. MIYAMOTO
PATRICK ADAMS	STANLEY M. CHOW

STATE OF Ar Kunsas	
foregoing instrument on behalf of	Day, 2010, before me personally appeared own to be the person described, and who executed the LS. Compound as as, and acknowledged that he she executed the same as
his/her free act and deed.	Same:
AMBER B. EVANS NOTARY PUBLIC-STATE OF ARKANSAS FAULKNER COUNTY My Commission Expires 08-06-2011	Notary Public, State of My Commission expires: 8 4 3011

March 1988 And Anna Carlo Carl

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2014-254

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE NON-RESIDENT PRESCRIPTION DRUG OUTLET REGISTRATION IN THE STATE OF COLORADO OF US COMPOUNDING, INC., REGISTRATION NO. OSP 5611,

Respondent Pharmacy

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and US Compounding, Inc. ("Respondent Pharmacy") to resolve all matters pertaining to Board Case Number 2014-254, as follows:

FINDINGS AND CONCLUSIONS

- The Board has jurisdiction over Respondent Pharmacy, its registration as a non-resident prescription drug outlet, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to provisions of the Pharmacists. Pharmacy Businesses, and Pharmaceuticals Act at Title 12, Article 42.5, C.R.S. (2013).
- 2 Respondent Pharmacy was originally registered in the State of Colorado on or about February 24, 2006, being issued registration number OSP 5611, and has been so registered at all times relevant to this disciplinary action.
- 3. Respondent Pharmacy's address of record with the Board and current location is 1270 Dons Lane, P.O. Box 2709, Conway, Arkansas 72033.
- 4. Respondent Pharmacy admits these findings and hereby waives any further proof in this or any other proceeding before the Board regarding the following facts.
- In or about December 2012, the Board mailed an affidavit to Respondent Pharmacy and requested that Respondent Pharmacy sign the affidavit to confirm that Respondent Pharmacy is aware of Colorado law and that it will not distribute prescription drugs into Colorado without valid, patient-specific prescription orders. The affidavit was signed by Respondent Pharmacy on December 27, 2012.
- 6. On or about November 1, 2013, Respondent Pharmacy distributed a prescription drug into Colorado pursuant to a prescription order that was not patient-specific.

7. Respondent Pharmacy admits that its conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Rules and provides grounds for disciplinary action against Respondent Pharmacy's Colorado registration as a prescription drug outlet:

Colorado Revised Statutes

12-42.5-123. Unprofessional conduct - grounds for discipline.

- (1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:
- (c) Has violated:
 - (I) Any of the provisions of this Article, including commission of an act declared unlawful in section 12-42.5-126;
 - (II) The lawful rules of the board; or
 - (III) Any state or federal law pertaining to drugs.
- (k) Has failed to meet generally accepted standards of pharmacy practice.
- **12-42.5-124. Disciplinary actions**. (1) The board may deny or discipline an applicant, licensee, or registrant when the board determines that the applicant, licensee, or registrant has engaged in activities that are grounds for discipline.

12-42.5-130. Nonresident prescription drug outlet-registration.

- (2) The registration requirements of this section apply only to a nonresident prescription drug outlet that only ships, mails, or delivers, in any manner, drugs and devices into this state pursuant to a prescription order.
- 8. The Board finds and concludes, and Respondent Pharmacy agrees, that based upon Respondent Pharmacy's above-described violations of the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances.

DISPOSITION

9. Fine with Surcharge. Pursuant to §12-42.5-124(5)(a)(I), C.R.S., Respondent Pharmacy shall pay a fine of One Thousand Dollars and No Cents (\$1,000.00). Respondent Pharmacy understands and acknowledges that, pursuant to §24-34-

Fig. 1. Section 1. Programme (as a programme programme programme programme)

- 108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall impose an additional surcharge of 10% of this fine. Respondent Pharmacy shall therefore pay a total amount of One Thousand One Hundred Dollars and No Cents (\$1,000.00). The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent Pharmacy submits this signed Final Agency Order to the Board.
- 10. <u>Compliance</u>. Respondent Pharmacy shall only dispense and deliver prescriptions into Colorado pursuant to valid, patient-specific prescription orders.
- 11. Other Requirements. Through its undersigned Authorized Representative, Respondent Pharmacy acknowledges and agrees that, as a condition of this Final Agency Order, Respondent Pharmacy shall:
 - a. promptly pay all its own fees and costs associated with this Final Agency Order;
 - b. comply fully with this Final Agency Order; and
 - c comply fully with the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmaceuticals and pharmacists in the State of Colorado.
- 12. <u>Violations</u>. Time is of the essence to this Final Agency Order. It is the responsibility of Respondent Pharmacy to take all appropriate steps to comply fully with this Final Agency Order. Respondent Pharmacy acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under §12-42.5-124(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of its registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Pharmacy to comply with all terms and conditions of this Final Agency Order.
- 13. Advisements and Waivers. Through its undersigned Authorized Representative, Respondent Pharmacy enters into this Final Agency Order freely and voluntarily, after having the opportunity to consult with legal counsel and/or choosing not to do so. Respondent Pharmacy acknowledges its understanding that it has the following rights:
 - a. To have a formal notice of hearing and charges served upon it;
 - b. To respond to said formal notice of charges:
 - c. to have a formal disciplinary hearing pursuant to §§12-42.5-123 and 12-42.5-124, C.R.S.; and

d. To appeal this Board order.

Respondent Pharmacy freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for Board's limiting the action taken against it to the sanctions imposed herein.

- 14. Acknowledgments. The undersigned Authorized Representative of Respondent Pharmacy has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel and/or choosing not to do so that Respondent Pharmacy understands the legal consequences and agrees that none of the terms or conditions herein is unconscionable. Respondent Pharmacy is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Pharmacy further acknowledges that it is not entering into this Final Agency Order under any duress.
- 15. Integration and Severability. Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties in this case. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.
- 16. <u>Public Record</u>. Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.
- 17. **Board Order.** This Final Agency Order shall become an order of the Board when it is accepted and signed by the Program Director or authorized Board representative.
- 18. Effective Date. This Final Agency Order shall become effective upon (a) mailing by first-class mail to Respondent Pharmacy at Respondent Pharmacy's address of record with the Board, or (b) service by electronic means on Respondent Pharmacy at Respondent Pharmacy's electronic address of record with the Board. Respondent Pharmacy hereby consents to service by electronic means if Respondent Pharmacy has an electronic address on file with the Board.

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ACCEPTED AND AGREED BY

Michigan St. St. Co., London S

Respondent Pharmacy

Authorized Representative / Title Dated: 2/27/14
Subscribed and sworn to before me in the County of, State, State
of this <u>ale</u> day of <u>February</u> , 2014 by
Eddle Glover in his/her capacity as an
authorized agent of US Compounding, Inc.
Ellie Here * SHEWILSON * USU WINN
My commission expires: 10-31-31

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 12 day of 1/10/01/01, 2014.

State Board of Pharmacy

Chris Gassen

Program Director

CERTIFICATE OF SERVICE

US Compounding, Inc. Attn: Eddie Glover 1270 Dons Ln P.O. Box 2709 Conway, AR 72033

Agent of the Board

STATE OF MICHIGAN PECEIVED
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

ENERGY DIVERSON

In the Matter of

US COMPOUNDING INC License Number 53-01-008506 File Number: 53-14-132457 CONSENT ORDER AND STIPULATION

CONSENT GROER

An <u>Administrative Complaint</u>, hereafter Complaint, was executed on July 30, 2014, charging US Compounding Inc., hereafter Respondent Pharmacy, with having violated section 17768(2)(d) of the Public Health Code, 1978 PA 368, as amended. MCL 333 1101 et seg; and

Respondent Pharmacy has admitted, by Stipulation submitted herewith that the facts alleged in the Complaint are true and constitute a violation of the Public Health Code; and

The Disciplinary Subcommittee of the Michigan Board of Pharmacy. hereafter Disciplinary Subcommittee, has reviewed the Stipulation and, based upon the matters asserted therein, agrees that the public interest is best served by resolution of the outstanding Complaint, therefore.

IT IS FOUND that the facts alleged in the Complaint are true and constitute a violation of section 17768(2)(d) of the Public Health Code, subra

Accordingly.

IT IS ORDERED that for the cited violation of the Public Health Code.

Respondent Pharmacy is FINED in the amount of \$500,00 to be paid to the State of Michigan within 60 days of the effective date of this Gross.

IT IS FURTHER ORDERED that the fins shall be mailed to the Department of Licensing and Regulatory Affairs, Enforcement Division, Sanction Monitoring, P.O. Box 30189, Lansing, MI 48969. The fine shall be paid by check or money order, made payable to the State of Michigan, and the check or money order shall clearly display file number 53-14-132467.

IT IS FURTHER ORDERED that in the event Respondent Pharmacy violates any provision of this Order, the Disciplinary Subscrimittee may proceed to take disciplinary action pursuant to 1993 AACS R 338.1632 and section 16221(h) of the Public Health Code, supra

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IT IS FURTHER ORDERED that this Order shall be effective 30 days from the date signed by the Disciplinary Subcommittee as set forth below.

Dated 12-16-14

MICHIGAN BOARD OF PHARMACY

By Chaimerson Disciplinary Subcommittee

STIPLIATION

- 1. The facts alleged in the Complaint are true and constitute a violation of section 17768(2)(d) of the Public Health Code, <u>supra</u>
- 2. Respondent Pharmacy understands and intends that by signing this Stipulation Respondent Pharmacy is waiving the right, pursuant to the Public Health Code, the rules promulgated thereunder and the Administrative Procedures Act of 1969, 1969 PA 306 as amended: MCL 24.201 et seg. to require the Department of Licensing and Regulatory Affairs, hereafter Department to prove the charges set forth in the Complaint by presentation of evidence and legal authority and Respondent Pharmacy is waiving the right to appear with an attorney and such witnesses as Respondent Pharmacy may desire to present a defense to the charges
- 3. Respondent Pharmacy and the Department further agree that this matter is a public record required to be published and made available to the public pursuant to section 11(1)(a) of the Michigan Freedom of Information Act. 1976 PA 442.

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as amended, MCL 15.241(1)(a); and this sotion will be reported to the National Practitioner's Data Bank, and any other entity as required by state or federal law, in accordance with 42 USC 11101-11152.

- Pharmacy who supports this proposal and the Department's representative are both free to discuss this matter with the Disciplinary Subcommittee and recommend acceptance of the resolution set forth in the Consent Order.
- 5. This Consent Order is approved as to form and substance by Respondent Pharmacy and the Department and may be entered as the final order of the Disciplinary Subcommittee in this cause.

CONTINUED ON NEXT PAGE

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This proposal is conditioned upon acceptance by the Disciplinary Subcommittee. Respondent Pharmacy and the Department expressly reserving the right to further proceedings without prejudice should the Consent Order be rejected.

AGREED TO BY

Carole H. Engle. Director
Bureau of Health Care Services
Department of Licensing and

Regulatory Affairs

AGREED TO BY

Edule (Bove

Authorized Representative for Respondent Pha macy

Dated:

15 - 75 - 16

osted 16/20/14

This is the final page of a <u>Consent Order and Stipulation</u> in the matter of US Compounding ind. File Number 53-14-132457 before the Disciplinary Subcommittee of the Michigan Board of Pharmany consisting of five pages, this page included

SDM

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY

DISCIPLINARY SUBCOMMITTEE

In the Matter of

US COMPOUNDING INC. License Number, 53-C1-008506

File Number 53-14-132457

ADMINISTRATIVE COMPLAINT

The Michigan Department of Licensing and Regulatory Affairs, hereafter

Complainant, by Carole H. Engle. Director. Bureau of Health Care Services, files this

Complaint against US Compounding Inc., hereafter Respondent Pharmacy, as follows:

The Michigan Board of Pharmacy hereafter Board is as

administrative agency established by the Public Health Code 1979 PA 368 as

amended; MCL 333.1101 et seg. Pursuant to section 17768 of the Public Health Code.

supra the Board's Disciplinary Subcommittee is empowered to discipline licensees for

violations of the Public Health Code.

2. Respondent is currently licensed to practice as a pharmacy in the

state of Michigan and has an address of record with Complainant of Conway, Arkansas

On October 22, 2008, the Colorado State Board of Pharmacy,

hereafter Colorado Board, executed a Stipulation and Final Agency Order against

Respondent Pharmacy which assessed a fine of \$5,750.00. The Goldrado Board's

action was based on Respondent Pharmacy's failure to provide the Colorado Board with

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a copy of its Drug Enforcement Administration registration and failure to submit data to the Prescription Drug Monitoring Program. A copy of the <u>Stipulation and Final Agency</u> Order, marked Exhibit A. is attached and incorporated

4. On March 12, 2014, the Colorado Board executed a <u>Stipulation and Final Agency Order</u> against Respondent Pharmacy which assessed a fine of \$1,100.00. The Colorado Board's action was based on Respondent Pharmacy distributing prescription drugs without obtaining valid patient-specific prescription orders. A copy of the <u>Supulation and Final Apency Order</u>, marked Exhibit B. is attached and incorporated

COUNT

The foregoing action of the Colorado Board as set forth above in paragraphs 3 and 4 evidences a pharmacy, manufacturer, or wholesale distributor which has had its license or federal registration limited, suspended or revoked or been subject to any other criminal, civil, or administrative penalty, and constitutes a violation of section 17768(2)(d) of the Public Health Code, subra.

Complainant requests that this Complaint be served upon Respondent Pharmacy and that Respondent Pharmacy be offered an opportunity to show compliance with all lawful requirements for retention of the license of compliance is not shown. Complainant further requests that formal proceedings be commenced pursuant to the Public Health Code rules promulgated thereunder, and the Administrative Procedures Act of 1969 MCL 24.201 et seq.

Pursuant to section 16231(7) of the Public Health Code, <u>supra</u> Respondent Pharmacy has 30 days from the date of receipt of this Complaint to submit a written response to the allegations contained herein. The written response shall be submitted to Complainant, Carole H. Engle. Director, Bureau of Health Care Services. Department of Licensing and Regulatory Affairs, P.O. Box 30670, Lansing MI 48909.

Pursuant to section 16231(8) of the Public Health Code <u>subral</u> Respondent Pharmacy's failure to submit a written response within 30 days, as noted above, shall be treated as an admission of the allegations contained herein and shall result in transmittal of this complaint directly to the Board's Disciplinary Subcommittee for imposition of an appropriate sanction.

DATED: 7-30-14

Carole H. Engle, Director

Attachments

This is the final page of an <u>Administrative Combiaint</u> in the matter of US Compounding inc. File Number 53-14-132457, before the Disciplinary Succommittee of the Michigan Board of Pharmacy, consisting of three pages, this page included.

BM

to Land Toward Control (Paragraphy) (Paragr

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Metro and Non-Metro: 800-627-3529

E-Mail Address: Pharmacy.Board@state.mn.us

Web Site: www.pharmacy.state.mn.us

PERSONAL & CONFIDENTIAL

May 28, 2015

Gabriel D. Mallard, Esq. The Health Law Firm One Cantrell Center 2800 Cantrell Road, Suite, 200 Little Rock, AR 72202

Re: In the Matter of US Compounding Inc.

License No. 264411

Dear Mr. Mallard:

Enclosed and served upon you in the above-referenced matter is the fully executed Stipulation and Consent Order issued by the Board of Pharmacy.

Sincerely,

Beth Ferguson, Pharm D, BCPS

Beth Sergusion

Deputy Director

Enclosure

cc: Hans Anderson, Assistant Attorney General, Attorney for Board of Pharmacy

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of US Compounding, Inc. License Number 264411

STIPULATION AND CONSENT ORDER

STIPULATION

US Compounding, Inc. ("Licensee"), and the Minnesota Board of Pharmacy Complaint Review Panel ("Panel") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

- 1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to license and regulate pharmacies and to take disciplinary action as appropriate.
- 2. Licensee holds a pharmacy license from the Board and is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. Licensee met with the Panel on February 12, 2015. The Panel was composed of Board member Bob Goetz. After a thorough review of the facts the Panel and Licensee have agreed this matter may be resolved with a Stipulation and Consent Order.

4. Licensee was represented by Gabriel D. Mallard, Esq. Hans A. Anderson, Assistant Attorney General, represented the Panel.

III.

FACTS

- 5. On August 2, 2002, the Board licensed Licensee as a non-resident pharmacy and on July 23, 2014, the Board licensed Licensee as a Wholesale Distributor.
- 6. On June 5, 2013, the Board sent Licensee a letter stating that licensure in Minnesota only allows Licensee to compound and dispense drug products pursuant to patient-specific prescriptions and that Licensee cannot provide compounded drugs to prescribers for office use.
- 7. From approximately April 2013 to September 2014, Licensee compounded and dispensed drug products into Minnesota without first obtaining patient-specific prescriptions. Licensee asserts it was acting in a good-faith effort.

IV.

LAWS

8. The Board asserts that Licensee's conduct described in section III. above constitutes a violation of Minn. Stat. § 151.071, subd. 2(9) (Minn. Stat. § 151.06, subd. 1(a)(7)(v) for conduct prior to July 1, 2014), Minn. Stat. § 151.071, subd. 2(7) (Minn. Stat. § 151.06, subd. 1(a)(7)(ix) for conduct prior to July 1, 2014), Minn. Stat. § 151.01, subd. 16a and subd. 35 (Minn. Stat. § 151.01, subd. 16 for conduct prior to July 1, 2014) and Minn. Stat. § 151.34(11). For purposes of the settlement of this matter only, and for no other purposes civil, administrative, or criminal, Licensee agrees that the disciplinary action described below may be imposed by the Board.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

- 9. The Board REPRIMANDS Licensee and imposes a CIVIL PENALTY in the amount of \$10,000.00. The civil penalty shall be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of this Order.
 - 10. The Board **CONDITIONS** Licensee's license as follows:
- a. <u>Policies and Procedures</u>. Within 120 days of the date of this Order, Licensee shall submit to the Board a copy of its Policies and Procedures for compounding and dispensing drug products into Minnesota pursuant to patient-specific prescriptions.
- 11. Upon Licensee's complete payment of the Civil Penalty described in Paragraph 9 above as well as Licensee's successful submission to the Board of its Policies and Procedures as described in Paragraph 10 above, the Board will administratively remove the Conditions from Licensee's license.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

12. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Panel may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

- a. The Panel shall schedule a hearing before the Board. At least 20 days before the hearing, the Panel must mail Licensee a notice of the violation(s) alleged by the Panel. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee shall submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.
- b. The Panel, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.
- c. Prior to the hearing before the Board, the Panel and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Panel and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Panel will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations, but may present argument concerning the appropriateness of additional discipline. Pursuant to this process, Licensee waives a hearing before an administrative law judge, discovery, cross-examination of adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.
- d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but does not limit the Board's authority to impose discipline for the violation. A decision by the Panel not to seek discipline when it first learns of a violation does not waive the Panel's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's license is in a suspended status.

- e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's license, a period of suspension, conditions of reinstatement, or revocation of Licensee's license.
- f. Nothing herein limits the Panel's or the Board's right to temporarily suspend Licensee's license as provided in Minnesota Statutes chapters 151 and 214, based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII.

ADDITIONAL INFORMATION

- 13. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.
- 14. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.
- 15. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter shall constitute the entire record and may be reviewed by the Board in its consideration of this matter.
- 16. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

- 17. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.
- 18. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it.
- 19. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

20. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the

Board pursuant to this Order is considered active investigative data on a licensed health professional, and as such, is classified as confidential data pursuant to Minnesota Statutes section 13.41, subdivision 4.

21. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

MINNESOTA BOARD OF PHARMACY COMPLAINT REVIEW PANEL

US COMPOUNDING, INC.

Licensee

Dated: 4/8/15

Board Member

Dated: 5 - 27 - 15

ORDER

Upon consideration of the Stipulation, the Board REPRIMANDS Licensee, imposes a CIVIL PENALTY, places CONDITIONS on Licensee's license, and adopts all of the terms described above on this 27^{104} day of M_{24} , 2015.

MINNESOTA BOARD OF PHARMACY

CODY WIBERG Executive Director